Navajo Nation Human Research Review Board Meeting Agenda

Meeting Date: 2023-05-16 Meeting Time: 9:00 AM

Location: Zoom

Associated with Reduced Outpatient

Hospitalizations - NNR-20.376 Dr. Hammitt; 4) Productive Use, Institutional Continuity Support Networks, ad Trust Building: The Challenges of Deploying Technological Solutions in Rural and Remote Communities - NNR-22.439 Dr. Ann-Perry Whitmer.

X. Announcements and Adjournments:

QUARTERLY REPORTS

1. NNR-02.094 PI: Mary Hoskin

Action for Health in Diabetes Look AHEAD

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2023 - March 31, 2023

2. NNR-16.247 PI: Bruce Bender

Creating an asthma collaboration to reduce childhood asthma disparities on the Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 16, 2023 - April 15, 2023 period

3. NNR-19.355 PI: Sally Davis

Healthy Places-Healthy People

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering February 20, 2023 - May 19, 2023 period

4. NNR-17.281 PI: Nanibaa' Garrison

Perspectives on Genetic Research in the Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) August 17, 2022-November 15, 2022, 2)

November 16, 2022 - February 21, 2023 periods

5. NNR-21.400 PI: Viola Hoskie

Shattering the Glass Ceiling: Cultivating Grit, Growth Mindset and Self-Efficacy in a Fourth and Fifth Grade Classroom

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1, 2023 - March 31, 2023 period

6. NNR-06.195 PI: James Deaton

National Indian Education Study 2007

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 16, 2023 - April 15, 2023 period

7. NNR-17.288 PI: Dana Dabelea

Tribal Turning Point (TTP)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 2023 - March 2023 period

8. NNR-19.349 PI: Tasha Seneca Keyes

Restorative Justice practices for improving school-based relationships

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 28, 2023 - April 22, 2023 period

9. NNR-20.380 PI: Regina Eddie

Examining School Wellness in American Indian Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 1, 2022 - March 31, 2023 period

10. NNR-21.425 PI: Wayne Morgan

Healthy Hooghans Pilot Project

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering 1) January 1, 2023 - March 31, 2023 period, 2)

October 19, 2022 - December 31, 2022 periods

11. NNR-97.018 PI: Laura Hammitt

A double Blinded, Controlled Study of the Efficacy, Immunogenicity, Safety and Tolerability, and Effectiveness of a Pneumococcal Conjugate Vaccine Containing 7 Serotypes (6B, 14, 19F, 23F, 18C, 4, and 9V) Compared to a Control Meningococcal C Vaccine in Navajo and Apache Indian Infants

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

12. NNR-04.151 PI: Laura Hammitt

A Phase 3 Study of MEDI-524 (Numax), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Navajo and White Mountain Apache Infants in the Southwestern United States

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

13. NNR-05.165 PI: Laura Hammitt

Long Term Impact of the Pneumococcal Conjugate Vaccine on Pneumococcal Nasopharyngeal Colonization and Immune Correlates for Disease Protection

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

14. NNR-05.174 PI: Allison Barlow

In-home Prevention of Substance Abuse Risk in Navajo Teen Families

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

15. NNR-09.253 PI: Laura Hammitt

Impact of 13-valent pneumococcal conjugate vaccine (PVC13) on pneumococcal disease and colonization among Native American communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

16. NNR-07.216 PI: Laura Hammitt

Rapid-response investigation of pediatric cases of invasive Haemophilus influenzae in Navajo American Children

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

17. NNR-11.325 PI: Laura Hammitt

Study of a vaccine for reducing ear and lung infections in children

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

18. NNR-11.332 PI: Kristen Speakman

Evaluation of an Edible School Garden Program; Evaluation of the Feast for the Future Community Visioning Program.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

19. NNR-15.232 PI: Laura Hammitt

Etiology of pneumonia and burden of pneumococcal pneumonia in hospitalized American Indian adults Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

20. NNR-16.261 PI: Laura Hammitt

Evaluation of maternal immunization and interventions to increase uptake of vaccines among expectant American Indian women

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

21. NNR-16.238 PI: Laura Hammitt

Active Bacterial Surveillance for Staphylococcus aureus on the Navajo and White Mountain Apache Reservations.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

22. NNR-16.264 PI: Allison Barlow

Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months, Part II: 18 Months

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

23. NNR-16.254 PI: Nicole Neault

Evaluation of NativeVision Year Round Program

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

24. NNR-17.282 PI: Laura Hammitt

A Study to Evaluate the Efficacy of Maternal Immuncation with RSV F vaccine in Preventing RSV Lower Respiratory Tract Infection in Young Infants (RSV-M-302)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

25. NNR-19.350 PI: Laura Hammitt

Surveillance for RSV and Other Respiratory Infections among Native American Children and Pregnant Women Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

26. NNR-19.354 PI: Allison Barlow

Cancer Care Project: Addressing Disparities in Cancer Education, Care and Outcomes in Native American Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

27. NNR-19.357 PI: Laura Hammitt

A Phase 3 Randomized, Double, Placebo-controlled Study to evaluate the Safety and Efficacy of MEDI 8897, a Monoclonal Antibody with an Extended Half-Life Against respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

28. NNR-19.364 PI: Jennifer Richards

Replication of Respecting the Circle of Life (RCL) - Teen Pregnancy Prevention Program with Navajo Youth and Families

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

29. NNR-20.374 PI: Laura Hammitt

Immunogenicity of H, Influenzae type b PRP-OMP vaccines in American Indian and Alaska Native Children (the HibVax Study)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

30. NNR-20.376 PI: Laura Hammitt

Convalescent Plasma to Limit Coronavirus Associated Complications: A Randomized Double-Blind, Controlled, phase 2 study Comparing the Efficacy and Safety of Human Coronavirus Immune Plasma (HCIP) vs. Control (SARS-CoV-2 non-immune) Plasma Among outpatients with Symptomatic COVID 19 (Treatment Study) Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

31. NNR-20.381 PI: Laura Hammitt

A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Find Study to Evaluate the Safety, Tolerability, Immunigenicity, and Efficacy of SARs-COV 2 RNA Vaccine Candidates Against COVID-19 in Healthy Adults (Short Title: Pfizer COVID-19 Vaccine Study)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

32. NNR-20.392 PI: Laura Hammitt

Protecting Native Families from COVID-19

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

33. NNR-21.405T PI: Emily Haroz

Pilot Evaluation of Psychological First Aid for Frontline Workers in American Indian/Alaska Native Communities

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

34. NNR-21.424 PI: Chelsea Lutz

Characterizing SARS-CoV-2 Vaccine Effectiveness Evidence of Infection, and Immunity among American Indian and Alaska Native Persons in the United States

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

35. NNR-22.445 PI: Joshuaa Allison-Burbank

Piloting + Connection is Medicine Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

36. NNR-22.448 PI: Catherine Sutcliffe

Pneumococcal carriage among Native Americans in the Southwest (the PNEU-CARE Study)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

37. NNR-22.449 PI: Ashley Lee

Dine' Household Water Survey

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

NEW PRESENTATION(S)

1. NNR-23.473 PI: Stephanie Klein

Characterization of Utahs live Interactive Teledermatology Outreach for Navajo Patients

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission - TABLED at April 18, 2023 Meeting, Use Agenda

item from 4-18-23 agenda packet; Date Received - 04/11/2023

2. NNR-23.467 PI: David Garcia

Advancing Liver Cancer Prevention for Arizona American Indian Communities

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission TABLED 3-28-23 Meeting Conditions Need

IRB of Record Letter. University of Arizona IRB of Record Letter attached.; Date Received - 03/14/2023

3. NNR-23.468 PI: Juliet Lee

Healthy Native Nations: Identifying Effective Alcohol Policies for American Indian Tribes

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of new Submission; Date Received - 04/06/2023

4. NNR-23.474 PI: Alark Saxene

The Role of Southwest Forests in the Social-Ecological Resilience of the Navajo (Din'e) Nation: A Case-Study of the Chuska Mountains and Defiance Plateau

Reason on Agenda: NEW

Description: Remarks: Request Review and Acceptance of New Study; Date Received - 05/01/2023

5. NNR-23.475 PI: Carma Claw

External Aid: The lived experiences of Dine Communities as Recipients

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 05/02/2023

6. NNR-23.476 PI: Kristin Mitchell

Formative work with medical providers and personnel in preparation for the NATIVE-RISE clinical trial Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of new Study; Date Received - 05/05/2023

RETURNING PRESENTATION(S)

1. NNR-18.316 PI: Deidre Hunter

Cultural Responsive Project Based Learning STEM Curriculum for Native American Classrooms

Reason on Agenda: Final Report

Description: Request Acceptance and Approval to Closed Study. Submittal of Thumb Drive to Navajo Research Office.

2. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 1, 2022 - December 31, 2022 period

Reason on Agenda: (Other)

Description: Request Acceptance and Approval of Revision 5.0 to MRI and PET/CT Imaging Consent Form.

3. NNR-11.342 PI: Joan O'Connell

Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data Infrastructure

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering May 15, 2023 - May 15, 2024 period

4. NNR-15.199 PI: Carmen George

REACH for Healthy Navajo Communities.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to modify store survey FVRx Store Feedback Survey.

5. NNR-17.277 PI: Denise Charron-Prochownik

Stopping Gestational Diabetes in Daughters and Mothers - Phase 2

Reason on Agenda: Quarterly Review

Description: Request Review and Approval of Quarterly Report covering February1, 2023-April 30, 2023 period

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Poster Presentation titled Relationship between food insecurity and a gestational diabetes risk reduction intervention: Outcomes among American Indian and Alaska Native adolescent and young adult female. at 2023 American Diabetes Association Scientific Sessions in June 2023.

6. NNR-19.332 PI: Gyan Nyaupane

Understanding the changing relationships of Indigenous peoples with their natural environments: A cross-cultural Study

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 2022 - January 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 2022 - January 2023 period

7. NNR-19.363 PI: Charlene Poola

Tribal Equine Assisted Psychotherapy: Building Youth Resilency through Horses

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 1, 2023 - January 31, 2024

period

Reason on Agenda: Annual Report

Description: Request Review and Acceptance of Annual Report covering February 1, 2022 - January 31, 2023 period

8. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination of two PowerPoint Presentations: 1) Preliminary Navajo Nation Water Hauling Survey Results, 2) Preliminary Navajo Nation Water Hauling Survey Results.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering March 17, 2022 - March 17, 2023 period

9. NNR-21.431 PI: Ashley Lee

Evaluation of Navajo Safe Water Access Projects

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of EN-SWAP Dissemination Plan

Reason on Agenda: (Other)

Description: Request Acceptance and Approval of Preliminary Findings

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

10. NNR-22.439 PI: Ann-Perry Witmer

Contextualization of Rural Infrastructure Systems for Improved Sustainability

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation Titled: "Applying Contextual Engineering to Engineering Needs for Bodaway Gap Chapter in the Area of Water and Energy" at the 11th International Conference on Engineering Education for Sustainable Development at Colorado State University, Fort Collins, CO on June 18-21, 2023

11. NNR-11.346 PI: Nicole Neault

Together on Diabetes Study: Evaluation of a pilot Diabetes Prevention and Management Program for American Indian Youth.

Reason on Agenda: Final Report

Description: Request Acceptance and Approval Of Final Study and Request to Close study.

12. NNR-18.307 PI: Laura Hammitt

Safety and Immunogenicity of V114 in Adults at Risk for Pneumonoccal Disease (Adult PCV15 Study)

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request Covering June 19, 2023 - June 19, 2024 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report of covering June 19, 2022 - June 19, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

13. NNR-19.343 PI: Laura Hammitt

Active Surveillance for Invasive Bacterial Disease Among Native Americans in the Southwest (US)

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request coverng June 18, 2023 - June 18, 2024 period

Reason on Agenda: Annual Report

Description: Request Review and Acceptance of Annual Report covering June 18, 2022 - June 18, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

14. NNR-21.414 PI: Laura Hammitt

Phase 3 Master Protocol to Evaluate additional Dose(s) of BNT162B2 in Healthy Individuals previoulsy Vaccinated with BNT162B2

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering June 22, 2023 - June 22, 202 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering June 22, 2022 - June 22, 2023 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

15. NNR-15.223 PI: Jennifer Richards

Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.

Reason on Agenda: Amendment

Description: Requesting Acceptance and Approval of Amendment to Revise Youth Outcomes Assessment to clarify answer options and correct minor grammatical errors.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

16. NNR-21.401 PI: Jennifer Richards

Evaluation of Azhee Bidziil (Strong Fathers) Program: Improving Outcomes Among Rural Fathers and their Families.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval Continuation Request covering June 15, 2023 - June 15, 2024 period

Page 12

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering June 15, 2022 - June 15, 2023 period

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract titled Evaluation of Azhe' 'e Bidziil (Strong Father) Program: Improving Outcomes Among Rural Fathers and their Families - Feasbility, Acceptability, and Preliminar Impacts" at Society for Prevention Research (CPR Conference on May 30-June 2, 2023 in Washington, DC.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

17. NNR-21.429 PI: Mary Cwik

Validation of the ASQ - AskSuicide Screening Questions (ASQ) Questionnaire, in the Navajo Area Indian Health Service (NAIHS) Health Care Setting

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to revision of Recruitment Flyer, with JHU name changes.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

18. NNR-22.457 PI: Joshuaa Allison-Burbank

Language is Medicine: A Language Nutrition Intervention to Prevent Development Delay in Dine Children Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Two (2) Abstracts for Conference Presentations: 1) symposium on Research in Child Language Disorders on June 1-3, 2023 in Madison, Wisconis; 2) Indigenous Home Visiting Meeting, on June 6-8, 2023, in Crystal City, Virginia.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

19. NNR-21.419 PI: Joshuaa Allison-Burbank

Project Safe Schools: Re-opening schools serving Native children and adolescents SAFELY

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation Titled: "Returning to School During Dikos Ntsaaigii (COVID)-19): Effects of the Pandemic on Din'e (Navajo) Students Learning and Mental Health" at Indigenous Peoples and Pandemics Conference at Oslo, Norway, on May 15-16, 2023.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering January 1 - March 31, 2023 period

SERIOUS ADVERSE EVENT

1. NNR-02.094 PI: Mary Hoskin

Action for Health in Diabetes Look AHEAD Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Unknown cause of Death

2. NNR-20.374 PI: Laura Hammitt

Immunogenicity of H, Influenzae type b PRP-OMP vaccines in American Indian and Alaska Native Children (the HibVax Study)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Croup, mild dehydration, bronchiolitis

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Bronchiolitis, Hypoxia

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Bronchiolitis, RSV+

Last Page and End of Agenda